CHAPTER 7

ENVIRONMENTAL IMPACTS FROM AQUACULTURE FACILITIES

7.1 INTRODUCTION

The purpose of this chapter is to present information EPA has collected relating to environmental impacts from aquaculture facilities, with a focus on the larger concentrated aquatic animal production (CAAP) facilities that are in the scope of EPA's final CAAP rule. Environmental effects associated with types of production systems and segments of the industry that are not in the scope of EPA's final rule (e.g., pond systems; molluscan shellfish operations) are addressed to a very limited extent by this chapter. In addition, EPA has not attempted to prioritize or otherwise characterize environmental risks from any particular impact, nor has EPA attempted to review in this chapter industry, State, and other regulations and programs to mitigate potential environmental impacts from CAAP facilities (see Chapter 1 of the Technical Development Document for a discussion of existing regulations affecting this industry).

A summary overview of CAAP pollutant loadings, including a brief review of facility characteristics, effluent quality, and range of annual pollutant loadings, is presented in Section 7.2. A limited review of selected literature relating to the water quality and aquatic ecosystem impacts from these loadings is presented in Section 7.3. References are provided in Section 7.4. The sources cited in this chapter include EPA engineering analyses that can be found in the Technical Development Document (USEPA, 2004) accompanying EPA's final CAAP rule; materials submitted with public comments and other materials provided by stakeholders; and a range of published technical literature.

7.2 CAAP INDUSTRY DISCHARGES

7.2.1 Description of Industry

The aquaculture industry encompasses several major types of production systems and a wide range of sizes and species. According to EPA census data, there are over 3,200 aquatic animal production systems in the United States, with approximately 260 facilities subject to EPA's final regulation. Effluent quality varies with facility characteristics including type of production system, facility size, and ownership.

Aquatic animal production facilities that are in-scope of the final CAAP rule represent considerable variation in facility size, species, production system type, ownership, and geographic distribution. The size of in-scope facilities varies by annual production levels. Aquatic animal production facilities produce a variety of species in a number of different production systems, including ponds, flow-through systems, recirculating systems, net pens, and open water culture. Furthermore, aquatic animal production facilities are owned by commercial and non-commercial (e.g., state and federal governments, tribes, non-profits, and research institutions) entities and vary in their location throughout the United States. Refer to Chapter 3 of the Technical Development Document for a detailed summary of the in-scope facilities.

7.2.2 Discharges of Solids, Nutrients, and BOD

7.2.2.1 Introduction

Solids, nutrients, and BOD primarily arise from uneaten feed and waste produced by the fish. A number of earlier investigations to characterize aquaculture effluents have been performed (e.g., as described in Regional Aquaculture Centers, (RAC), 1998. The following sections focus on characterizing concentrations from studies reported in the literature and EPA sampling observations. The following examples are representative of in-scope facilities because they examine facilities that are similar to facilities in-scope of the final CAAP rule, in terms of size, production systems, and general operation. A later section provides estimates of annual mass loadings from facilities that are in-scope of the final CAAP rule.

7.2.2.2 Flow-through Systems

Effluents from flow-through systems can be characterized as continuous, high-volume flows containing low pollutant concentrations. Effluents from flow-through systems are affected by whether a facility is in normal operation or whether the tanks or raceways are being cleaned. Waste levels can be considerably higher during cleaning events (Hinshaw and Fornshell, 2002; Kendra, 1991).

Hinshaw and Fornshell (2002) compiled effluent values reported in the literature and provide ranges for various water quality constituents. They report average BOD levels to be 2.0 mg/L during normal operations, with levels increased by approximately 10 times as settleable solids were disturbed during cleaning. Likewise, solids increased from normal levels of ≤35 mg/L to a range of 61.9-1000 mg/L for facilities during cleaning. Concentrations of total phosphorus (TP) reported were ≤0.13 mg/L, but increased by three times during cleaning[2]. Estimates of ammonia-nitrogen ranged from 0.01 to 1.52 mg/L, illustrative of the fact that ammonia concentrations are based on a number of factors (e.g., stocking density, water retention time, and time of feeding).

As an example of changes in effluent quality during cleaning, Kendra (1991) examined effluent quality during cleaning events at two hatcheries. At each hatchery, total suspended solids, total phosphorus, and BOD increased during cleaning. At one hatchery, TSS increased from 1 mg/L to 88 mg/L and total phosphorus increased from 0.22 mg P/L to 4.0 mg P/L. BOD increased from 3 mg/L to 32 mg/L at one facility, and at the other from 4 mg/L to 12 mg/L.

Boardman et al. (1998) conducted a study after surveys conducted in 1995 and 1996 by the Virginia Department of Environmental Quality (VDEQ), 2002, revealed that the benthic aquatic life of receiving waters was adversely affected by discharges from several freshwater trout farms. Three trout farms in Virginia were selected to represent fish farms throughout the state. This study was part of a

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[2]Solids that are captured in quiescent zones or other in-process settling that occurs at flow-through system facilities are periodically cleaned out of the production units (i.e., quiescent zones, tanks, or raceways) to maintain optimal water quality in the process water. Accumulated solids, which can be about 60 to 70 percent of the total volume at a facility, are swept or vacuumed from the production units and conveyed to settling basins for treatment. The duration of the cleaning events range from a few minutes to about ½ hour or longer, depending on the size of the area being cleaned. The frequency of the cleaning events also varies based on the volume of solids that accumulate over time.

larger project to identify practical treatment options that would improve water quality both within the facilities and in their discharges to receiving streams.

After initial sampling and documentation of facility practices, researchers and representatives from VDEQ discovered that although pollutants from the farms fell under permit regulation limits, adverse effects were still being observed in receiving waters. Each of the farms was monitored from September 1997 through April 1998, and water samples were measured for dissolved oxygen (DO), temperature, pH, settleable solids (SS), TSS, total Kjeldahl nitrogen (TKN), total ammonia nitrogen (TAN), 5-day biochemical oxygen demand (BOD_5), and dissolved organic carbon (DOC).

Sampling and monitoring at all three sites revealed that little change in water quality between influents and effluents occurred during normal conditions at each facility (Table 7-1). The average concentrations of each regulated parameter (DO, BOD_5, TSS, SS, and AN) were below their regulatory limit at each facility; however, raceway water quality declined during heavy facility activity like feeding, harvesting, and cleaning. During these activities, fish swimming rapidly or employees walking in the water would stir up solids that had settled to the bottom. During a 5-day intensive study, high TSS values were correlated with feeding events. TKN and ortho-phosphate (OP) concentrations also increased during feeding and harvesting activities. Overall, most samples taken during this study had relatively low solids concentrations, but high flows through these facilities increased the total mass loadings.

Table 7-2 describes the water quality data for two flow-through systems sampled as part of EPA's data collection efforts at CAAP facilities. These results are comparable to those presented above. For both facilities there was little change between the influent and treated production effluent concentrations. However, pollutant concentrations in Off-Line Settling Business (OLSB) effluent was much higher than both influent and unit discharge waste effluent concentrations, and the OLSB flow rates were about one percent of the treated production unit discharge (Table 7-2).

7.2.2.3 Recirculating Systems

Recirculating systems have internal water treatment components that process water continuously to remove waste and maintain adequate water quality. Overall, recirculating systems produce a lower volume of effluent than flow-through systems. The effluent from recirculating systems usually has a relatively high solids concentration in the form of sludge. The sludge is then processed into two streams—a more concentrated sludge and a less concentrated effluent (Chen et al., 2002). Once solids are removed from the system, sludge management is usually the focus of effluent treatment in recirculating systems.

In a study describing the waste treatment system for a large recirculating research facility in North Carolina, Chen et al. (2002) characterize effluent at various points in the system (Table 7-3). Approximately 40% of the solid waste produced by this particular facility is collected in the sludge collector and composted. The remaining 60% of the solids are treated with two serial primary settlers (septic tanks) and then a polishing pond (receiving pond). Table 7-4 describes the water quality data for one recirculating system sampled as part of EPA's data collection efforts at CAAP facilities.

Table 7-1
Water Quality Data for Three Trout Farms in Virginia

Parameter	FARM A			FARM B			FARM C		
	Inlet	Within Farm	Outlet	Inlet	Within Farm	Outlet	Inlet	Within Farm	Outlet
Flow (mgd)	1.03–1.54[a] (*1.18*)[b]			4.26–9.43 (*6.39*)			9.74–10.99 (*10.54*)		
BOD_5 (mg/L)	0–1.2 (*0.7*)	0.5–3.9 (*1.5*)	0.96–1.9 (*1.3*)	0–1.4 (*0.5*)	0.3–7.2 (*2.1*)	0.6–2.4 (*1.2*)	0–2.0 (*1.1*)	0.4–7.5 (*2.5*)	0.5–1.8 (*1.3*)
DO (mg/L)	9.2–14.2 (*10.6*)	3.2–13.3 (*7.0*)	5.7–9.5 (*8.5*)	8.2–11.5 (*10.5*)	5.8–10.8 (8.6)	6.8–9.6 (*7.9*)	9.4–10.6 (*10.5*)	4.8–9.7 (*7.6*)	7.2–9.4 (*8.1*)
pH (SU)	7.1–7.4 (*7.3*)	7.0–7.4 (*7.2*)	7.3–7.8 (*7.5*)	7.3–7.6 (*7.5*)	7.2–7.6 (*7.4*)	6.9	7.3	7.1–7.6 (*7.3*)	7.8
Temp (ºC)	10.5–13 (*12.2*)	11.5–15 *13*)	11–15.5 (*12.9*)	6–12.5 (*9.7*)	6–14 (*9.1*)	5–16.5 (*11.4*)	8.5–13.5 (*10.5*)	8–14 (*11.0*)	8.5–14 (*10.4*)
TSS (mg/L)	0–1.1 (*0.2*)	0–30.4 (*3.9*)	0.8–6 (*3.2*)	0–1.8 (*0.5*)	0–43.7 (*5.3*)	1.5–7.5 (3.9)	0–1.5 (*0.3*)	0–28 (*7.1*)	4.1–62 (*6.1*)[c]
SS (mg/L)	ND		0–0.04 (*0.02*)	ND		0.01–0.08 (*0.04*)	ND		0.04–0.08 (*0.07*)
NH_3-N (mg/L)	0.6	0.2–1.1 (*0.5*)	0.5–0.6 (*0.6*)	0.2	0.06–1.1 (*0.5*)	0.45	0.03	0.03–2.2 (*0.4*)	0.02–0.17 (*0.1*)
DOC (mg/L)	0.93–4.11 (*2.1*)	0.9–7.9 (*2.9*)	1.5–2.4 (*1.9*)	0.91–2.56 (*1.6*)	1.2–8.1 (*2.7*)	1.2–3.1 (*1.9*)	1.1–2.7 (*2.0*)	1.1–11.1 (*2.4*)	1.5–3.8 (*2.3*)

[a] When available the range of values has been reported
[b] The average is indicated using italics.
[c] Two outliers were discarded for calculation of mean.
ND: Non-detect
Source: Boardman et al., 1998.

Table 7-2
Flow-through Sampling Data Table

Parameter	Facility A			Facility B		
	Inlet	OLSB Effluent	Bulk Water Discharge	Inlet	OLSB Effluent	Final Effluent
Flow (mgd)	192.4	0.914	91.4	2.481–2.777	0.017	2.481–2.777
BOD (mg/L)	ND (4)[a]	56.0–185.0[b] (*125.70*)[c]	3.50–4.20 (*3.85*)	ND (2)	13	ND (2)
pH (SU)	7.98–8.14 (*8.05*)	6.11–6.58 (*6.43*)	7.50–7.83 (*7.72*)	7.73–8.06 (*7.93*)	7.27	7.93–8.19 (*8.03*)
TSS (mg/L)	ND (4)	44.0–78.0 (*63.0*)	ND (4)	ND (4)	38	ND (4)
TP (mg/L)	0.7–0.25 (*0.14*)	8.32–11.10 (*9.81*)	0.15–0.25 (*0.21*)	0.02–0.03 (*0.03*)	0.36	0.03–0.07 (*0.05*)

[a] ND: Non-detect, the minimum level is listed in parenthesis.
[b] When available the range of values has been reported.
[c] The average is indicated using italics.
Source: USEPA sampling data. (Tetra Tech, 2002a)

Table 7-3
Water Quality Characteristics of Effluent at Various Points in the Waste Treatment System of Recirculating Aquaculture Systems at the North Carolina State University Fish Barn[a]

Parameter	Primary settling 1 inflow	Primary settling 2 inflow	Septic tank 2 outflow	Receiving pond effluent
COD (mg/L)	1043	690	409	153
TSS (mg/L)	752	364	205	44
TS (%)	0.22	0.18	0.16	0.11
NH_3-N (mg/L)	2.96	2.42	3.42	0.12
NO_2 -N (mg/L)	5.35	31.17	44	1.93
NO_3 -N (mg/L)	109	78.5	36.4	8.2
TKN (mg/L)	50.3	47.5	37.7	8.94
TP (mg/L)	28.6	22.7	17.6	4.95
PO_4 -P (mg/L)	5.98	11.5	12.2	3.68

[a] Results are from sampling conducted 4 wk after startup of the waste handling system. Flow from the system into the receiving pond for the sampling period was 15.5 m^3/d.
Source: Chen et al., 2002.

Table 7-4
Recirculating System Sampling Data

Parameter	Facility C	
	Inlet	Discharge
Flow (mgd)	0.22	0.22
BOD (mg/L)	ND (2)[a]	35.0–48.0[b] (*42.0*)[c]
pH (SU)	7.8	6.97–7.25 (*7.15*)
TSS (mg/L)	ND (4)	26.0–60.0 (*42.80*)
TP (mg/L)	ND (0.01)	8.58–10.50 (*9.32*)

[a] ND: Non-detect, the minimum level is listed in parenthesis.
[b] When available the range of values has been reported.
[c] The average is indicated using italics.
Source: EPA sampling data. (Tetra Tech, 2001b)

7.2.2.4 Net Pen Systems

Although net pen systems do not generate a waste stream like other production systems, they do have a continuous, diluted discharge because of the tides and currents that provide a continual supply of high-quality water to flush wastes out of the system. In summarizing much of the 'Brooks' monitoring data in Puget Sound, Nash (2001) indicated that statistically significant increases in soluble (i.e., water column) nitrogen have been detected at salmon farms in Puget Sound, albeit infrequently, with no statistically significant increases 30 m downstream. Nash (2001) indicated that the maximum un-ionized ammonia levels were 0.0004 mg/L in comparison to a 4-day chronic water quality criterion of 0.035 mg/L (at a pH of 8 and 15°C). Nash also reported that in Puget Sound, dissolved (water column) inorganic nitrogen (DIN) ranged from 0.3 to 1.9 mg/L, while the maximum DIN increase due salmon farms was 0.09 mg/L.

Strain et al. (1995) estimated the nitrogen and phosphorus loadings in waters near Letang (New Brunswick, Canada) from 22 salmon farms by scaling the output from a fish growth model. Their estimates indicate nitrogen concentration increases from 0.03 to 0.07 mg/L and phosphorus increases from 0.0047 to 0.011 mg/L that are attributed to salmon aquaculture. Nitrogen, phosphorus, and BOD loadings from these salmon farms are the largest anthropogenic source of nitrogen, phosphorus, and BOD according to Strain et al. (1995).

7.2.2.5 Estimated Annual Loads for In-scope Flow-through and Recirculating Facilities

Estimated annual baseline loads for in-scope flow-through and recirculating facilities are presented in Figures 7-1 through 7-4. EPA used a facility-specific approach for estimating pollutant loads. EPA obtained detailed, facility-level information for a sample of potentially in-scope facilities

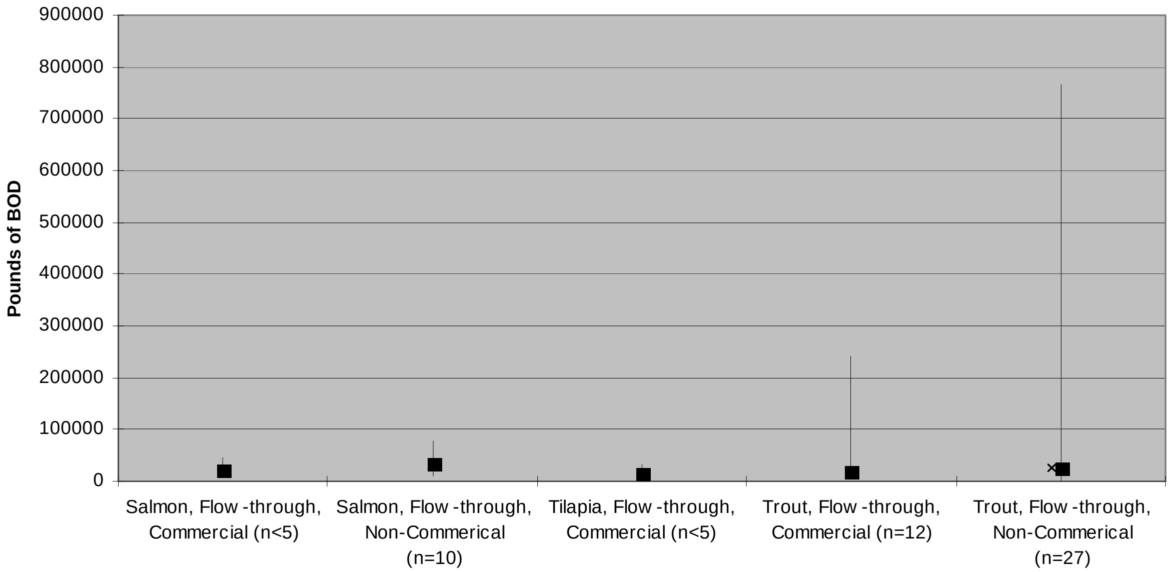

Figure 7-1. Estimated Baseline Loads of BOD for In-scope Flow-through and Recirculating Facilities. The minimum value is indicated by the lowest point of the line, the median by the square, and the maximum value by the highest point of the line. The number of facilities on which the minimum, median, and maximum values are based is indicated in parentheses under each group label.

Please see Section 7.2.2.5 and Chapter 10 of the Technical Development Document for more information.

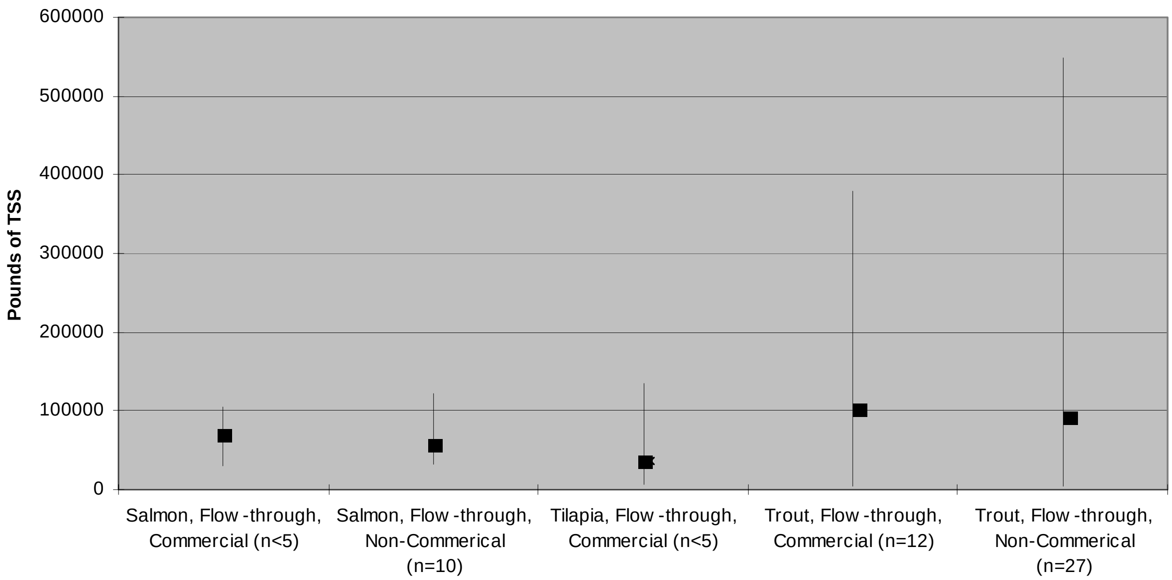

Figure 7-2. **Estimated Baseline Loads of TSS for In-scope Flow-through and Recirculating Facilities.** The minimum value is indicated by the lowest point of the line, the median by the square, and the maximum value by the highest point. The number of facilities on which the minimum, median, and maximum values are based is indicated in parentheses under each group label.

Please see Section 7.2.2.5 and Chapter 10 of the Technical Development Document for more information.

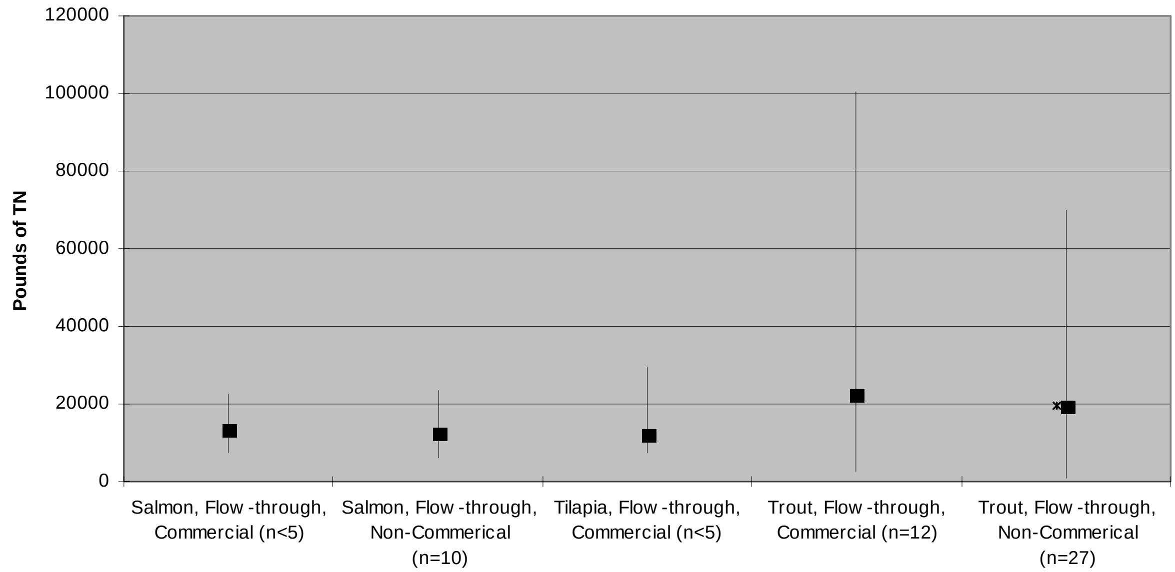

Figure 7-3. Estimated Baseline Loads of Total Nitrogen for In-scope Flow-through and Recirculating Facilities. The minimum value is indicated by the lowest point of the line, the median by the square, and the maximum value by the highest point of the line. The number of facilities on which the minimum, median, and maximum values are based is indicated in parentheses under each group label.

Please see Section 7.2.2.5 and Chapter 10 of the Technical Development Document for more information.

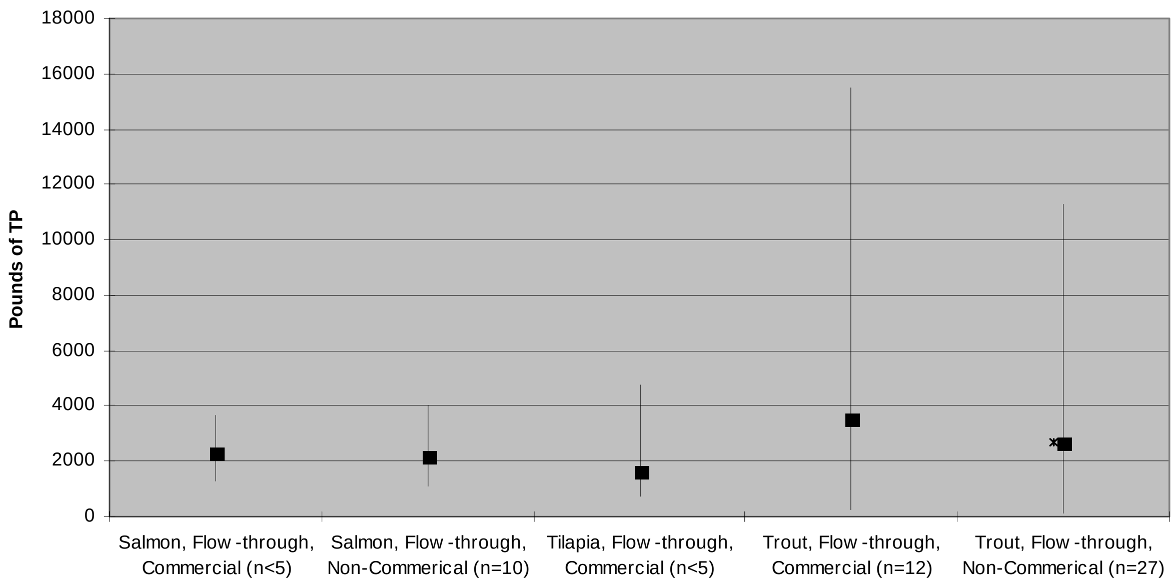

Figure 7-4. Estimated Baseline Loads of Total Phosphorus for In-scope Flow-through and Recirculating Facilities. The minimum value is indicated by the lowest point of the line, the median is represented by the square, and the maximum value is indicated by the highest point of the line. The number of facilities on which the minimum, median, and maximum values are based is indicated in parentheses under each group label.

Please see Section 7.2.2.5 and Chapter 10 of the Technical Development Document for more information.

through detailed AAP survey (USEPA, 2002a). EPA analyzed the detailed survey information, specifically information about feed inputs from which baseline loads for TSS, BOD, total nitrogen (TN), and TP could be estimated. Refer to Chapter 10 of the Technical Development Document for additional information.

7.2.3 Metals and Feed Additives/Contaminants

Metals may be present in CAAP wastewaters due to a variety of reasons. They may be used as feed additives, occur in sanitation products, or may result from deterioration of CAAP machinery and equipment. EPA has observed that many of the treatment systems used within the CAAP industry provide substantial reductions of most metals since most of the metals can be adequately controlled by controlling solids. Trace amounts of metals are added to feed in the form of mineral packs to ensure that the essential dietary nutrients are provided. Examples of metals added as feed supplements include copper, zinc, manganese, iron (Snowdon, 2003). Estimated baseline loads of metals and other feed additive/contaminants for in-scope facilities are summarized in Hochheimer et al., 2004. These loads were estimated as a function of TSS loads, using data obtained from samples collected by EPA during three sampling episodes (see Tetra Tech, 2001a, 2001b, and 2002a for detailed information on these sampling episodes) performed for the proposed rule. For this analysis, EPA set the analyte concentration in samples in which the analyte was not detected equal to one-half the detection limit of the analytical method used. From the sampling data, EPA calculated net TSS and metals concentrations at different points in the hatcheries. EPA then calculated metal-to-TSS ratios (in mg of metal per kg of TSS), based on net concentrations calculated above, and removed negative and zero ratios from the sample. Finally, basic sample distribution statistics were calculated to derive the relationship between TSS and each metal. Refer to Chapter 10 of the Technical Development Document for more information (USEPA, 2004).

Two substances, astaxanthin and canthaxanthin, are added to feed of farmed fish to improve consistent coloring of fish tissue. Astaxanthin and canthaxanthin have been widely used in northwestern Europe and North America, particularly for the artificial coloration of the flesh of salmonids during the later stages of grow-out operations (GESAMP, 1997). Two organisms, phaffia yeast (*Phaffia rhodozyma*) and haematococcus algae meal (dried *Haematococcus pluvialis*), produce astaxanthin and are certified by the FDA as approved color additives in fish feed (21 CFR 73.355 and 73.75). Pure astaxanthin, phaffia yeast, or haematococcus algae meal can be added to fish feed to induce the desired coloration in fish. *Phaffia rhodozyma* yeast naturally synthesizes astaxanthin during fermentation.[3] EPA has not attempted to quantify potential loads for these additives.

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[3]The European Commission Scientific Committee for Animal Nutrition (SCAN) examined the use of astaxanthin-rich *Phaffia rhodozyma* yeast in salmon and trout feed. In this report, the Committee noted that although safety aspects for the yeast were satisfactorily demonstrated, questions on effects of the active ingredient, astaxanthin, on the environment, remained an open question, despite assertions by the company that there was no need to study excreted residues because astaxanthin is present in nature and the product is a true (dead) yeast and as such an accepted feed ingredient (SCAN, 2002a). Regarding canthaxanthin, SCAN recommended in a 2002 opinion that the maximum permitted concentrations of canthaxanthin in feed be reviewed to ensure consumer safety (SCAN, 2002b; the committee was not asked to address the potential impact of canthaxanthin use on the environment and as a result there is no reference to this aspect of the assessment in the 2002 opinion). In 2003, the European Union amended permitted canthaxanthin levels in feed for salmonids and other animals in order to provide greater protection for consumers' health (Commission Directive 2003/7/EC of 24 January 2003, as reported in the Official Journal of the European Commission, January 25, 2003).

Several efforts have been made to evaluate aquaculture feed contaminants. As part of a recent investigation of organic contaminants in farmed salmon, Hites et al. (2004) analyzed thirteen samples of commercial salmon feed from Europe and North and South America for organochlorine contaminants. The authors found that while concentrations in feed were quite variable, they observed that concentrations in feed purchased from Europe were significantly higher than those in feed purchased from North and South America, possibly reflecting lower contaminant concentrations in forage fish from the coastal waters of North and South America as compared with those from the industrialized waters of Europe's North Atlantic (Hites et al., 2004). The U.S. Geological Survey (USGS) has sampled and is analyzing the occurrence of metal and organochlorine contaminant residues in commercial feeds purchased by the U.S. Fish and Wildlife Service hatcheries as a result of nutritional problems that were observed at some FWS hatcheries (USGS, n.d.). The results were being analyzed in late 2003 (J. Bayer, USGS, personal communication with L. McGuire, U.S. EPA, December, 2003 (McGuire, 2004)). EPA developed crude estimates of polychlorinated biphenyls (PCBs) in baseline loads for in-scope facilities, as summarized in Hochheimer et al., 2004.

7.2.4 Other Contributions and Releases

Maintenance of the physical plant of aquaculture facilities can generate organic materials that may contribute to water quality degradation (NOAA, 1999). For example, the activity of cleaning fouling organisms from net pens can contribute solids, BOD, and nutrients, although these inputs are generally produced only over a short period of time. Cleaning algae from flow-through raceway walls and bottoms similarly generates pollutants in effluent.

Cultured fish themselves may be lost from facilities because of decomposition of carcasses or scavenging by birds, mammals, and fish (Nash, 2001). Leakage may occur from small holes in net-pens, during handling, or during transfer of fish to another pen, and fish may also be lost as a result of operator error, predation, storms, accidents, and vandalism. One author writes:

> "It is widely known among commercial fish culturists that when fishes are held within nets in a body of water, a certain portion of fish assumed to be in cages disappears...this unexplained loss of fishes has been recognized for decades....Even today, commercial fish culturists continue to lose important numbers of salmonid fishes from cages in salt water, estimated to range from 10% to as much as 30%....Fish disappear even when there are no tears in the netting, the cages are covered, and daily inspections of cages are made...this loss can have economic importance - not only because of lost fish ("shrinkage") but also because food provided for these "phantom" fish often falls through the bottom netting and is wasted, such that assumed feeding rates and food conversions thus are both inflated." (Moring, 1989)

Based on his study of losses from net-pen facilities in Puget Sound, the author attributed losses to decomposition of carcasses, particularly during disease outbreaks; scavenging by birds, mammals, and fishes, and to a lesser extent, escapes, when cage netting remains intact (Moring, 1989). Various estimates of numbers of escaped fish from some net-pen facilities in the U.S. have been noted elsewhere (e.g., USEPA, 2002b).

EPA did not attempt to quantify other contributions and releases such as those described above from facilities in the scope of EPA's final regulation.

7.2.5 Drugs and Pesticides

By providing food and oxygen, AAP facilities can produce fish and other aquatic animals in greater numbers than natural conditions would allow. This means that system management is important to ensure that the animals do not become overly stressed, making them more vulnerable to disease outbreaks. When diseases do occur, facilities might be able to treat their populations with drugs.

FDA/Center for Veterinarian Medicine (CVM) regulates animal drugs under the Federal Food, Drug, and Cosmetic Act (FFD&CA). Operators producing aquatic animals that are being produced for human consumption must comply with requirements established by the U.S. Food and Drug Administration (FDA) with respect to the drugs that can be used to treat their animals, the dose that can be used, and the withdrawal period that must be achieved before the animals can be harvested. Four categories of drugs are used in aquaculture: (1) six commercial drugs currently approved for specific species, specific diseases, and at specific doses or concentrations; (2) investigational new animal drugs which are used under controlled conditions under an Investigational New Animal Drug (INAD) application; (3) the extralabel use of FDA-approved drugs under the provisions of the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA); and (4) drugs designated by FDA as low regulatory priority. Pesticides are also used to control animal parasites and aquatic plants at CAAP facilities

FDA/CVM approves new animal drugs based on scientific data provided by the drug sponsor. These data include environmental safety data that are used in an environmental risk assessment for the drug (Eirkson et al., 2000). Approved drugs have already been screened by the FDA to ensure that they do not cause significant adverse public health or environmental impacts when used in accordance with label instructions. See Section 7.3.3 for more information on FDA/CVM's environmental review process.

Currently, there are only six approved drugs for AAP species consumed by humans:

- Chorionic gonadotropin (Chorulon®)
- Oxytetracycline (Terramycin®)
- Sulfadimethoxine, ormetoprim (Romet-30®)
- Tricane methanesulfonate (Finquel® and Tricaine-S)
- Formalin (Formalin-F®, Paracide-F® and Parasite-S®)
- Sulfamerazine®

Investigational new animal drugs (INADs) are those drugs for which FDA has authorized use on a case-by-case basis to allow a way of gathering data for the approval process (21 USC 3606(j)). Quantities and conditions of use are specified. FDA, however, sometimes relies on the NPDES permitting process to establish limitations on pollutant discharges to prevent environmental harm.

Extralabel drug use is restricted to use of FDA-approved animal and approved human drugs by or on the lawful order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship. Specific conditions governing the extralabel use of drugs are established in 21 CFR Part 530. Specific conditions and provisions in 21 CFR Part 530 include those relating to compounding of approved new animal and approved human drugs, extralabel use in food-producing and non-food producing animals, safe levels and analytical methods, and specific drugs, families of drugs, and substances prohibited for extralabel use in animals. As stated in 21 CFR Part 530, extralabel use is limited to treatment modalities when the health of an animal is threatened or suffering or death may result from failure to treat. Extralabel uses that are not permitted include uses that result in any residue which may present a risk to public health and uses that result in any residue above an established safe level, safe concentration or tolerance. Additionally, AMDUCA prohibits the use of an FDA approved drug in or on any animal feed. See 21 CFR Part 530 for more detail on extralabel use conditions and limitations.

Unapproved new animal drugs are sometimes used in discrete cases where the FDA exercises its regulatory discretion. In determining whether a compound can be used without a New Animal Drug Application (NADA), FDA considers human food safety (if for use in food animals/fish), user safety and any other impacts of the unapproved use. Regulatory discretion does not constitute an approval by the Agency nor an affirmation of their safety and effectiveness. The FDA is unlikely to object to the use of any of these drugs if the substances are used under specific indications, at the indicated levels, and according to good management practices. In addition, the product should be of an appropriate grade for use in food animals (FDA, 1997). The user of any of the low regulatory compounds is responsible for meeting all local, state and federal environmental requirements.

The FDA does not require labeling for low-priority use for chemicals that are commonly used for non-drug purposes even if the manufacturer or distributor promotes the chemical for the permitted low-priority use. However, a chemical that has significant animal or human drug uses in addition to the low-priority aquaculture use must be labeled for the low-priority uses if the manufacturer or distributor uses promotion or other means to establish the intended low-priority use for the product. Additional labeling requirements are available from the FDA (FDA, 1997).

Pesticides may also be used to control animal parasites and aquatic plants and may be present in wastewaters from CAAP facilities.

Aquatic animal production facilities use a number of drugs and pesticides for a variety of reasons. Refer to Table B-1 in Appendix B for more specific information about drugs and pesticides used at aquatic animal production facilities and their generally reported uses.

MacMillan (2003) estimates that between 50,000 and 70,000 pounds of antibiotic active ingredient are sold each year for use in the aquaculture industry (0.3-0.4% of all antibiotics used in animal agriculture). For a summary of the total amount of drugs and pesticides used during 2001 by aquatic animal production facilities that completed detailed surveys, refer to Hochheimer and Meehan, 2004a.

7.2.6 Pathogens

CAAP facilities are not considered a source of pathogens that adversely affect human health. CAAP facilities culture cold-blooded animals (fish, crustaceans, mollusks, etc.) that are unlikely to harbor or foster such pathogens (MacMillan et al., 2002). EPA sampling data also supports this assertion (Tetra Tech, 2001a, 2001b; Tetra Tech, 2002a). Although it is possible for CAAP facilities to become contaminated with human pathogens (e.g., by contamination of facility or source waters by wastes from warm-blooded animals) and, as a result, become a source of human pathogens, this is not considered a substantial risk in the United States (MacMillan et al., 2002).

7.3 IMPACTS OF CAAP INDUSTRY DISCHARGES

7.3.1 Impacts from Solids, Nutrients, BOD, Metals, and Feed Contaminants

As described in more detail in Section 7.2, CAAP facility effluents can contribute nutrients (nitrogen and phosphorus), suspended solids, and BOD to receiving waters. Impacts associated with CAAP facility discharges include stimulation of algal and aquatic vascular plant growth, sediment oxygen demand, and a variety of chemical/biochemical processes that consume oxygen. The following sections first describe general aquatic ecosystem effects of discharges of solids, nutrients and BOD on aquatic ecosystems and then summarize recent literature reporting observations of AAP and/or CAAP facility discharges on aquatic ecosystems.

7.3.1.1 General Aquatic Ecosystem Effects

Solids (i.e., total suspended solids or TSS) are discharged from CAAP facilities both as suspended and settleable forms, primarily from feces and uneaten feed. Since TSS in effluents from CAAP facilities contains a high percentage of organic content, these solids can contribute to eutrophication and oxygen depletion (when microorganisms decompose the organic matter and consume oxygen). Suspended solids can also degrade aquatic ecosystems by increasing turbidity and reducing the depth to which sunlight can penetrate, which may decrease photosynthetic activity and growth of aquatic vascular plants and algae. Increased suspended solids can also increase the temperature of surface water because the particles may absorb heat from sunlight. Excess TSS can also cause a shift toward more sediment-tolerant species, carry nutrients and metals, and adversely affect aquatic insects that are at the base of the food chain (Schueler and Holland, 2000). As sediment settles, it can smother fish eggs and bottom-dwelling organisms, interrupt the reproduction of aquatic species, and destroy habitat for benthic organisms (USEPA, 2000). Suspended solids have been associated with effects on fish including reduced food consumption by certain life-stages of species (Breitburg, 1988; Redding et al., 1987; Gregory and Northcote, 1993).

Nutrients in the CAAP discharge can stimulate the growth of algae and other aquatic plants. Although algae and aquatic plants produce oxygen as a by-product of photosynthesis, they are net consumers of oxygen during periods of respiration when photosynthesis is not occurring due to absent or very limited sunlight. Many of the organic solids discharged from CAAP facilities settle rapidly and decompose at the sediment-water interface, which is termed sediment oxygen demand (Schueler and Holland, 2000). As discussed above, solids may lead to increased water temperatures, which ultimately decreases oxygen (warmer water has lower oxygen saturation levels). Other chemical and biochemical reactions, such as nitrification, also consume oxygen. The combination of eutrophication, plant growth, sediment oxygen demand, warming, and chemical or biochemical reactions may lead to changes in local or downstream dissolved oxygen. Often the net change is a lowering of oxygen levels available for aquatic and benthic organisms. Dissolved oxygen is essential to the metabolism of all strict aerobic aquatic organisms and its distribution in aquatic environments affects chemical, biological, and ecological processes (Wetzel, 1983).

Nitrogen at CAAP facilities can come from several sources. The largest contributor of nitrogen in effluents from CAAP systems comes from fish feed and feces (Avault, 1996). In CAAP facilities, nitrogen is mainly discharged as ammonia, nitrate, and organic nitrogen. Organic nitrogen decomposes in aquatic environments into ammonia and nitrate. Ammonia can be directly toxic to aquatic life, affecting hatching and growth rates of fish. However, ammonia is not usually found at toxic levels in CAAP discharges.

CAAP facilities release phosphorus in both the solid and dissolved forms. The dissolved form, generally as orthophosphate, is more readily available to plants and bacteria, which require phosphorus for their nutrition (Henry and Heinke, 1996). Excessive amounts of orthophosphate in the aquatic environment increase algae and aquatic plant growth, especially in freshwater environments where phosphorus is more likely to be a limiting nutrient. Although the solid form of phosphorus is generally unavailable, depending on the environmental conditions (e.g., availability of oxygen), some phosphorus may be slowly released from the solid form.

CAAP discharges to receiving waters of feed contaminants include metals and organochlorines and are discussed in Section 7.2.3. There is limited evidence that these contaminants adversely affect aquatic ecosystems in the United States under current practices. In an examination of the potential for heavy metal accumulation beneath net-pen farms in the Pacific Northwest, sediment concentrations of zinc, an essential trace element added to salmon feeds as part of the mineral supplement, were found to be typically increased near salmon farms (Nash, 2003). However, environmental factors (e.g., sediment sulfide concentrations), natural attenuation, advances in feed formulations, and existing net-pen benthic monitoring requirements are asserted to mitigate the potential for toxic levels to occur (Nash, 2003; Brooks and Mahnken, 2003a and 2003b). Although EPA is aware of recent interest in contaminants found in salmonid feed and farmed salmon (e.g., USGS, n.d.; Hites et al., 2004), EPA is aware of no peer-reviewed studies of the effects of releases of organochlorine contaminants in aquaculture facility wastes to receiving waters and limited evidence that such releases may pose an ecological risk. Easton et al. (2002) cite unpublished 1987 data from British Columbia indicating that benthic organisms around net-pen facilities contained elevated levels of polychlorinated biphenyls (PCBs) originating from salmon feed but no indication that these levels posed an ecological risk was provided. Internal documents prepared by the Pennsylvania Department of Environmental Protection also report elevated levels of PCBs in a small number of sediment, fish, and invertebrate samples from receiving water environments at several Pennsylvania hatcheries (McGuire, 2004).

Discharges of approved drugs and pesticides and other treatments used at aquaculture facilities may also impact aquatic ecosystems. For example, releases of copper compounds, used as antifoulants in raceways, tanks, and on net-pens, may lead to receiving water effects including changes to dissolved oxygen levels as algae die from exposure (Cornell, 1998). Nash (2003) concluded that potential risk from elevated sediment copper concentrations from marine net-pen anti-fouling compounds could be significantly reduced both by environmental factors (e.g., sediment sulfide concentrations, natural attenuation processes), as well as management practices such as washing nets at upland facilities and properly disposing of the waste in an approved landfill. Section 7.3.3 discusses in more detail literature regarding environmental effects of approved drugs.

7.3.1.2 Recent Literature

The previous section describes in a general sense the role that excess solids, nutrients, BOD, and feed contaminants could play in aquatic ecosystems. Studies discussed in this section include several site-specific studies related to aquatic ecosystem effects of effluent discharges from aquaculture facilities. Other literature describing aquatic ecosystem effects of facility discharges has been described elsewhere (e.g., work reported in RAC, 1998; USEPA, 2002b, Appendix E: "Literature Review for AAP Impacts on Water Quality").

Loch et al. (1996) examined the effects of three large trout flow-through facilities in North Carolina on macroinvertebrate species diversity. Their data showed that species richness was significantly decreased below the outfalls of the facilities. Samples did show that richness did increase further downstream. These data indicate that effluents did reduce water quality, even at 1.5 km further downstream, although to a lesser extent. The authors noted that impacts were seasonal, and that water quality and taxa richness improved during the winter. The authors also noted that sewage fungus (which they defined as a community of organisms that consist mainly of bacteria and ciliated protozoans and is the product of concentrated organic matter) "was present in great abundance at Site 2 of each trout farm."

In contrast, Fries and Bowles (2002) examined aquatic impacts associated with a large CAAP facility located on the San Marcos River in Texas, which is designated by the Texas National Resource Conservation Commission as exceptional for aquatic life and recreation. On average, this CAAP facility produces four million largemouth bass fingerlings, one million channel catfish fingerlings, 12,000 kg live forage for captive broodstock, and 67,000 rainbow trout (winter only) each year. Based on the data covering a period from October 1996 to July 1998, the authors concluded that "the hatchery effluent did not substantially affect downstream water quality and benthic communities, despite the relatively high total suspended solids and chlorophyll-a levels in the effluent." The authors noted "...that sportfish hatchery operations can have negligible effects on receiving waters, even in environmentally sensitive systems."

In the 1970s, Big Platte Lake in Michigan, which is fed by the Platte River, was experiencing periods of calcium carbonate formation that were reducing lake transparency (also called "whiting"), as well as other symptoms of eutrophication including reduced macroinvertebrate communities and disappearance of sensitive vegetation. Because the watershed is mostly undeveloped, a possible explanation of these changes in lake conditions was phosphorus loadings from nonpoint sources, effluents from the Platte River State Fish Hatchery, salmon smolts dying in outmigration, and returning adult salmon deaths in the river. It was estimated that the hatchery was contributing approximately 33% of the phosphorus load into the lake in the late 1970s (Whelan, 1999). In its 1980 NPDES permit, the hatchery was required to take steps to reduce phosphorus loads in its effluent. However, subsequent court cases found that significant changes in facility operation would be required to mitigate the impairment of Big Platte Lake. Beginning in 1998, the hatchery took further actions to improve lake conditions. The hatchery's 1988 NPDES permit restricted water use to 166 million liters per day, with a maximum discharge of 200 kg of phosphorus per year, and TSS limits of 1,000 kg/day. Through the use of low phosphorus fish food, improvements in waste removal, deepening of treatment ponds, and changes in fish migration, the hatchery now contributes only 5% of the annual phosphorus loading to the lake. Maximum transparency in the lake has increased from an average of 3.5 meters to 5 meters or greater. Severe whiting events continue to occur during the summer months, although these loss of transparency problems are less frequent since 1988. Studies and renovations of the hatchery are estimated to further improve water conditions in the future (Whelan, 1999).

Memoranda, correspondence, and discussion with staff of the South Central Region of the Pennsylvania Department of Environmental Protection (PA DEP) indicate environmental impacts at several CAAP facilities (200,000 to 400,000 lbs annual production) in Pennsylvania. PA DEP provided data and reports documenting adverse impacts of hatchery effluents in receiving spring-fed streams. The materials described observations and/or concerns including those about discharges of carbonaceous BOD and TSS and other pollutants, and results of aquatic biological surveys showing adverse impacts in hatchery receiving waters. While recognizing unique characteristics of these hatcheries (all located on limestone spring creeks and all capture most, if not all, of the streamflow) and seasonality of these impacts, staff biologists were concerned about adverse environmental impacts observed at several sites (Botts, 1999; Embeck, 2000; Botts, 2001; McGuire, 2003).

EPA performed a review of literature to document reported water quality impacts from net pen facilities (Mosso et al., 2003). Literature showed that organic enrichment may result from uneaten feed or feces that accumulate on sediment below and near the perimeter of net pens. McGhie et al. (2000) showed that the rate of accumulation is affected by the amount of uneaten feed and feces from the production facility as well as the amount of material transported away from the site largely as a result of water current velocities. Effects of organic enrichment include changes in benthic communities such as recruitment of organic carbon tolerant species and diminution of organic carbon sensitive species. These changes may result in reduced diversity and abundance or organisms (Nash, 2001; Findlay et al., 1995; McGhie et al., 2000; La Rosa et al., 2001). In addition, organic loading to the sediment might exceed existing benthos capacity and might become anoxic. Anoxia can lead to further changes in benthic communities as well as to sediment chemistry changes, including increased sulfide concentrations and decreased redox potential, which are common at net pen facilities. Literature examined shows that the nearfield impacts to benthic communities are common within 100 meters of the net-pen perimeter. Many net pen operators routinely fallow net pen sites on a regular basis (Bron et al., 1993) primarily for disease and parasite control, but also to reduce benthic impacts. For example, many Maine net pen operators raise single year classes at a site and fallow the site for about 30 to 90 days after harvest, depending on temperature, currents, and benthic conditions (Tetra Tech, 2002b and 2002d).

In addition to literature described above and elsewhere, several Total Maximum Daily Load (TMDL) reports describe aquaculture facilities' contributions to pollutant loads in specific watersheds. The following paragraphs describe several such TMDL documents. The brief descriptions below are not meant to imply that TMDLs involving aquaculture facilities are prevalent, but rather only to illustrate that several have been developed, and to illustrate the types of pollutants that are addressed.

In 2002, the Virginia Department of Environmental Quality's Virginia Water Resources Research Center submitted a report, *Benthic TMDL Reports for Six Impaired Stream Segments in the Potomac-Shenandoah and James River Basins*. This document reports on a Total Maximum Daily Load (TMDL) calculation performed for six impaired stream segments in Virginia. These stream segments were listed as impaired on EPA's 1998 303(d) report following benthic macroinvertebrate surveys. Critical stressors to these stream segments were identified, and the report concludes that aquaculture effluents were confirmed as the primary source of the organic solids that impaired these short segments (0.02 to 0.8 miles). The aquaculture facilities constituted from 86.2 percent (11,481 pounds per year out of 13,325 total pounds per year for the particular stream) to 99.6 percent (4,438 pounds per year out of 4,455 total pounds per year for the particular stream) of the organic solids loading in these sections of primarily first-order, spring-fed streams. To put these loads into perspective, the organic load (defined as 60 percent of the measured TSS load from a facility) to the different streams ranged from 1,823 pounds per year (94.9 percent of the total load in the particular stream) to 72,477 pounds per year (99.4 percent of the total load in the particular stream) (VDEQ, 2002).

A number of TMDLs have been developed to address water quality concerns associated with pollutant loads from sources including aquaculture in the Snake River region Idaho. The Middle Snake River, Idaho, is a 150 km stretch of the Snake River that has been transformed from a free-flowing river to one with multiple impoundments, flow diversions, and increased pollutant loadings. These changes have led to significant alterations to river habitat, loss of native macroinvertebrate species, extirpation of native fish species, expansion of pollution-tolerant organisms, and excessive growth of macrophytes and algae. According to EPA (2002), 80 private and State-owned aquaculture facilities operate under federal NPDES permits, and over 20 additional facilities have applied for permits, in the Middle Snake River. These facilities supply approximately 80% of the trout consumed in restaurants in the United States (USEPA, 2002c). TMDLs in various stages of completion which address loadings from many of the aquaculture facilities in this region include the Upper Snake Rock TMDL, the Billingsley Creek TMDL, and the Cascade Reservoir TMDL. Pollutants addressed in these TMDLs include total phosphorus total suspended solids.

In a TMDL for a small reservoir in Utah, aquaculture was identified as a significant contributor to an impaired water, resulting in a recommended load reduction of 15% (13.2% of the total load reduction recommended) from the hatchery discharging to the impaired reservoir (Utah DEQ, 2000). According to the TMDL report:

> "Mantua Reservoir is a small reservoir located within the community of Mantua in east Box Elder County, Utah...Mantua Reservoir is highly productive (i.e., has a large amount of nutrients such as nitrogen and phosphorus), creating problems that include dense beds of aquatic plants, algal blooms, low dissolved oxygen (DO), and high pH. The high productivity is primarily due to the lake's shallowness and excess loading of nutrients from the watershed....The Mantua Fish Hatchery is the only permitted point source in the watershed....[and] is a significant contributor of nutrients to the Reservoir, adding an estimated 304.4 kg/Y TP (31% of total load)..."

7.3.2 Impacts from Other Releases

Other releases from facilities (discussed in Section 7.2.4) include materials related to maintenance activities, loss of fish via decomposition of carcasses, and escapes. In some cases, escaped cultured organisms may not be native to the receiving water and at certain levels may pose an environmental risk. Scientists and resource managers have recognized aquaculture operations as a potential source of concern with respect to non-native species issues (ADFG, 2002; Carlton, 2001; Goldburg et al., 2001; Naylor et al., 2001; Lackey, 1999; and Volpe et al., 2000). It is important to note, however, that many non-native fishes are introduced intentionally. For example, non-native sport fish species are a large and important component of a number of state recreational fishery programs. Horak (1995) reported that "[forty]-nine of 50 state recreational fishery programs use nonnative sport fish species, and some states are almost totally reliant on them to provide recreational fishing." This section does not address such intentional releases. In addition, scientists have also highlighted the need for careful assessment of potential environmental risks associated with the possible future use of genetically modified organisms in aquatic animal production (e.g., Hedrick, 2001; Reichardt, 2000; Howard et al., 2004).

Many states have developed requirements specific to potential escapes of non-native organisms from aquaculture facilities (see, for example, the tilapia discussion under Section 7.3.2.2) and/or have developed aquatic nuisance species (ANS) management plans to address non-natives in their state. ANS management plans identify goals or objectives for addressing ANS and strategic actions or tasks to accomplish the goals or objectives. For example, an objective might be to prevent the introduction of new ANS into state waters. A strategic action to accomplish this might be to identify those ANS that have the greatest potential to infest state aquatic resources. As part of this effort, states might identify existing and potential pathways that facilitate new ANS introductions. A task that might be used to accomplish the strategic action might be to develop a regional listing of ANS and evaluate the potential threat posed by these organisms to aquatic resources in the state. ANS management plans are available on the Aquatic Nuisance Species Task Force website at *http://www.anstaskforce.gov*.

The following sections describe general issues relating to effects of non-native aquatic organisms (Section 7.3.2.1) and specific discussions relating to non-native issues specifically related to aquaculture operations (Section 7.3.2.2).

7.3.2.1 General Aquatic Ecosystem Effects

Non-native aquatic organisms in North America can alter habitat, change trophic relationships, modify the use and availability of space, deteriorate gene pools, and introduce diseases. Non-native fish introduced to control vegetation, such as carp or tilapia, can destroy native vegetation. Destruction of exotic and native vegetation can result in bank erosion, degradation of fish nursery areas, and acceleration of eutrophication as nutrients are released from plants. Common carp (*Cyprinus carpio*) reduce vegetation by direct consumption and by uprooting as they dig through the substrate in search of food. Digging increases turbidity in the water (AFS, 1997; Kohler and Courtenay, n.d.). Non-native species may also cause complex and unpredictable changes in community trophic structure. Communities can be changed by explosive population increases of non-native fish or by predation of native species by introduced species (AFS, 1997). Spatial changes may result from overlap in the use of space by native and non-native fish, which may lead to competition if space is limited or of variable quality (AFS, 1997).

Genetic variation may be decreased through inbreeding by species being produced in a hatchery. If these species are introduced to new habitat, they may lack the genetic characteristics necessary to adapt or perform as predicted. There is also a possibility that native gene pools may be altered through hybridization from non-native species. However, hybridization events in open waters are rare (AFS, 1997; Kohler and Courtenay, n.d.). Finally, diseases caused by parasites, bacteria, and viruses may be transmitted into an environment by non-native species. For example, transfer of diseased non-native fish from Europe is believed to be responsible for introducing whirling disease in North America (Blazer and LaPatra, 2002).

7.3.2.2 Recent Literature

The following discussions of Atlantic salmon and tilapia illustrate the potential or actual role of aquatic animal production in releases of non-native species. These organisms are discussed here because they are known to be cultured at facilities such as those in the scope of the final CAAP Rule. In the case of Atlantic salmon, EPA received many comments regarding potential environmental impacts of farmed, non-native salmon escaping from net pens and is aware that these species are raised in marine net pens in both the Puget Sound and New England areas. Tilapia species are known to be raised at CAAP facilities in the scope of the final regulation, and again, EPA is aware of concerns that have been raised with the potential establishment of this group of non-North American species.

It should be noted that other aquaculturally raised organisms have been identified as a source of concern in some environments by resource managers and scientists from a non-native species perspective (e.g., carp, Asian oysters). For example, grass carp (*Ctenopharyngodon idella*) have spread rapidly in the last few decades from research projects, escapes from natural ponds and aquaculture pond facilities, legal and illegal interstate transport, releases by individuals and groups, stockings by Federal, State, and local government agencies, and natural dispersion from introduction sites (Pflieger, 1975; Lee et al., 1980; Dill and Cordone, 1997). Grass carp remove vegetation, which can result in the elimination of food, shelter, and spawning substrates for native fish (Taylor et al., 1984). Black carp (*Mylopharyngodon piceus*) provide a cheap means for controlling trematodes in catfish ponds, but they feed on many different mollusks when released to the environment. Silver carp (*Hypophthalmichthys molitrix*) were discovered in natural waters in 1980, "probably a result of escapes from fish hatcheries and other types of aquaculture facilities" (Freeze and Henderson, 1982, as cited in Fuller et al., 1999). Bighead carp (*Hypophthalmichthys nobilis*) first appeared in open waters (Ohio and Mississippi rivers) in the early 1980s, "likely as a result of escapes from aquaculture facilities (Jennings 1988, as cited in Fuller et al., 1999). Both carp have been identified as species of significant concern to aquatic resource managers (Schomack and Gray, 2002). Again, however, it is important to stress that carp are mainly raised in pond aquaculture systems, and that pond systems are not in the scope of EPA's final regulation.

Atlantic Salmon

Escapement of Atlantic salmon (*Salmo salar*) from net pens off the East and West Coasts of the United States and in British Columbia has been well documented. Potential concerns associated with Atlantic salmon escapes include possible impacts on wild salmon from disease, parasitism, interbreeding, and competition. In areas where the salmon are exotic, most concerns do not focus on interbreeding with other salmon species. Rather, they center on whether the escaped salmon will establish feral populations, reduce the reproductive success of native species through competition, alter the ecosystem in some unpredictable way, or transfer diseases (EAO, 1997).

However, a comprehensive evaluation of risks has concluded that the escape of Atlantic salmon pose very little or no risk to the environment of the Pacific Northwest, including through the mechanisms of colonization of salmonid habitat, competition with native species for forage, predation on indigenous species, and hybridization with other salmonids (Nash, 2001). Furthermore, another recent report finds little to no risk to "evolutionarily significant units" (ESUs) of Puget Sound chinook salmon and Hood Canal summer-run chum salmon arising from Atlantic salmon farms in Puget Sound (Waknitz et al., 2002). Authors of the latter study qualify their conclusion by stating that significant expansion of the industry may increase risks and some of the potential impacts might need to be reconsidered. Nevertheless, it should also be noted that Alaska Department of Fish and Game (ADFG) and others assert that Atlantic salmon may adversely effect native populations of Pacific salmon through mechanisms including colonization, habitat destruction, and competition (ADFG, 2002; Goldburg et al., 2001). ADFG recommends a gradual transition along the Pacific Coast to only land-based Atlantic salmon farming and storage operations. Research by Volpe and others (Volpe, 2000, 2001a, 2001b) suggests that Atlantic salmon may be capable of colonizing and persisting in coastal British Columbia river systems that are underutilized by native species.

In northeastern U.S., in contrast, aquaculture escapees were among the major threats to the Gulf of Maine distinct population segment (DPS) of Atlantic salmon identified by NOAA and USFWS ("Services") due to interactions between wild stocks and escapees. The Services noted that a large percentage of fish used at that time in aquaculture were of European origin and genetically different from native North American strains, and that North American strains used by the industry were genetically different from wild North American strains due to changes introduced through domestication. The Services further asserted that occurrences of adult escapees in Maine rivers were increasing commensurately with the growth of the aquaculture industry in Maine, and that government regulations and industry voluntary programs that existed at that time had not been effective in protecting wild stocks from aquaculture escapees. Considering scientific research including work suggesting that some level of introgression of European alleles may have already occurred, the Services concluded that "negative impacts to the DPS [from aquaculture escapes] can be reasonably anticipated to occur in Maine." The Services determined that the wild Gulf of Maine distinct population segment (DPS) of Atlantic salmon was in danger of extinction throughout its range and extended endangered status to this DPS (November 17, 2000; 65 FR 69459; available at http://www.nero.nmfs.gov/atsalmon/fr_fr.pdf).

Tilapia

The most commonly raised tilapia in the United States are blue (*Oreochromis aureus*), Nile (*O. niloticus*), Mozambique (*O. mossambicus*), and hybrids thereof. Native to Africa and the Middle East, tilapia have been introduced throughout the world as cultured species in temperate regions (Stickney, 2000). These freshwater fish of the family Cichlidae are primarily herbivores or omnivores. Feeding lower on the food chain has enhanced their popularity as a culture species (Stickney, 2000). Tilapia were first introduced to the Caribbean islands in the 1940s and then eventually were introduced to Latin America and the United States. In addition to production for foodfish, tilapia have been stocked in irrigation canals to control aquatic vegetation. Tilapia have also been used in the aquarium trade, as bait, as a sport fish, and as forage for warmwater predatory fish (Courtenay et al., 1984; Courtenay and Williams, 1992; Lee et al., 1980).

Tilapia have been found to be competitors with native species for spawning areas, food, and space (USGS, 2000a). Reports indicate that some streams, where blue tilapia are abundant, have lost most vegetation and nearly all native fish (USGS, 2000a). In Hawaii, tilapia is considered a threat to native species such as the striped mullet (*Mufil cephalus*; USGS, 2000b), and in California's Salton Sea area redbelly tilipia (*Tilapia zillii*) has been considered a significant factor in the decline of the desert pupfish (*Cyprinodon macularius*) (see Schoenherr, 1988).

Tilapia have also been introduced to other areas of the United States. Blue tilapia was evaluated for a number of beneficial uses by the Florida Game and Fresh Water Fish Commission. Although the Commission concluded that this species would be undesirable for stocking in Florida's public waters, the public removed fish from the study site, causing the tilapia to become established outside of the study site (Hale et al., 1995). Tilapia are now a commercially harvested species in Florida (Hale et al., 1995). During evaluation studies in North Carolina, blue and redbelly tilapia were inadvertently introduced into a reservoir. These species became established and led to the elimination of all aquatic macrophytes from the reservoir and declines in populations of several fish species (Crutchfield, 1995). In California, tilapia have become an important game fish, primarily in the Salton Sea, and their popularity with anglers is growing. Competition from and predation by Mozambique tilapia led to the extirpation of the High Rock Spring tui chub (*Gila bicolor*) from a California spring system. These tilapia were introduced from aquaculture facilities permitted by the California Department of Fish and Game (CDFG) in 1982. Inadequate screening of rearing facilities allowed tilapia to escape into the spring system (U.S. Department of Interior, Fish and Wildlife Service, 62 FR 49191-49193, September 19, 1997).

Because of its nonnative status, tilapia have been regulated by various States to prevent escapement and impacts on wild stocks of native species. Importation and movement of tilapia are regulated in the United States. According to Stickney (2000), the following states have some form of restriction on tilapia culture: Arizona, California, Colorado, Florida, Hawaii, Illinois, Louisiana, Missouri, Nevada, and Texas.

Several tilapia species and hybrids in the genus *Oreochromis* are raised at CAAP facilities in the scope of EPA's final regulation. EPA analysis suggests that the potential geographic distribution[4] of select tilapia species and hybrids may include California's San Joaquin Valley, southern California, southwestern Arizona, the Rio Grande River, and the Gulf Coast. Figures B-1 and B-2 (both in Appendix B) show, for all USGS 8-digit HUCs in the United States, the proportion of watershed area occupied by potential distribution, weighted by the number of distributional models (0-10 out of 10 models that had low underprediction errors) predicting presence in a grid cell. The potential geographic distribution of Mozambique, blue x Mozambique, and Wami River x Mozambique tilapia (Figures B-1a, B-1b, and B-1c) occurred in all these areas, in contrast to the more limited potential distributions of blue (Colorado River), Nile (Gulf Coast), and Wami River tilapia (southern Texas, Florida) (Figures B-2a, B-2b, and B-2c). Although these modeled distributions are considered robust, these should be regarded as a coarse view due to limited point-occurrence data. Furthermore, although it has been shown that convergent GARP predictions (locations where all models in the best-subset indicate potential presence) demonstrate high coincidence with areas of invasion/known occurrence, translating GARP output to a common numerical scale representing the likelihood of potential distribution, has not yet been done.

Data provided by facilities in the scope of EPA's final regulation indicate that several facilities raising one or more of the modeled species are located within the modeled potential distributions. As noted earlier, many States have established certain requirements relating to escapes of tilapia and/or non-native aquatic species in general; these States include some that fall within the modeled potential distribution area for tilapia. For example, most States in the area appear to require certain escape prevention measures. Mississippi State regulations, for instance, state that "[d]ue to the prolific nature of the Tilapia species, a fish barrier shall be designed to prevent the discharge of water containing Tilapia eggs, larvae, juveniles and adults from the permittee's property. Although Tilapia may not overwinter in Mississippi waters, precautions must be taken to limit their escape into native waters. This shall be accomplished by using a 1000 micron mesh screen" http://www.mdac.state.ms.us/library/agencyinfo/regulations/administration/AquacultureActivities.pdf]. On the other hand, it appears that while several States have established reporting requirements for escaped non-native organisms, several States do not have such reporting requirements. However, facility-specific requirements regarding escape prevention, escape reporting, or other prevention or mitigation measures may be established through a NPDES permit Hochheimer and Meehan, (2004b). For further details of EPA's analysis and review of State requirements, see Kluza and McGuire (2004) and Hochheimer and Meehan, (2004b).

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[4]The potential geographic distribution of a species in a region of interest may be estimated if the ecological niche of that species - defined based on nonrandom associations between point occurrence data for individuals of that species in its native range and ecological/environmental variables associated with the point occurrence data - as well as geographic information system coverages of the ecological/environmental variables for the region of interest, are available. EPA used the Genetic Algorithm for Rule-set Prediction (GARP) to model the potential geographic distribution of select tilapia species and hybrids. For further description of EPA's modeling analysis, see Kluza and McGuire (2004).

Other Issues Related to Escapes

As mentioned earlier, scientists have highlighted the need to carefully evaluate potential risks associated with the use of genetically modified (GM) organisms in aquatic animal production (e.g. Hedrick, 2001; Reichardt, 2000). Although the issue is being examined by commercial interests and under review by the Food and Drug Administration, there is no known current use of such organisms in U.S. aquaculture. Howard et al. (2004) studied mating competition and fitness between wild and genetically modified strains of Japanese medaka (*Oryzias latipes*); salmon growth hormones were added to a treatment group of male medaka to increase their size. The results showed GM males were more successful in mating with females, but produced offspring were less likely to survive than those sired by unaltered males. Howard et al. (2004) modeled these competing factors and the results suggest that if GM individuals are able to enter wild populations the transgene will spread, but will also ultimately lead to extinction of the population as offspring are less likely to survive[5].

7.3.3 Impacts from Drugs and Pesticides

7.3.3.1 Background

Drugs and pesticides are used at CAAP facilities as described in Section 7.2.5 for purposes including water quality maintenance, disinfection, anesthetization, and a variety of disease control and treatment purposes. Compounds reported in responses to EPA's detailed industry questionnaire to be used at CAAP facilities include AQUI-S, oxytetracycline, copper sulfate, formalin, hydrogen peroxide, and potassium permanganate and Chloramine-T.

Some drugs and pesticides used at CAAP facilities enter the environment with facility effluent following treatment. These compounds may affect non-target organisms in receiving environments, but any potential exposure depends on site-specific conditions and a number of general protections exist or have been instituted to mitigate potential impacts to non-target organisms. For example, approved drug and pesticide products are used only when needed for defined, specific purposes and for finite treatment durations. Furthermore, industry has developed a variety of quality assurance programs to promote a positive code of production practices that ensures a wholesome and safe product to consumers and the environment (Eirkson et al., 2000). In addition, FDA's environmental review processes result in drug label requirements, as necessary, that include directions on proper dilution before discharge and other conditions (e.g., filtration) that can control the amount of animal drug contained in effluents. FDA and EPA are also working on a formal agreement that would identify shared responsibilities for drug releases that pose an environmental risk.

FDA's Center for Veterinary Medicine (CVM), approves drugs for use in animals including aquatic animals under the Federal Food, Drug and Cosmetic Act (FFDCA). As part of the approval process, under the requirements of the National Environmental Policy Act (NEPA), CVM evaluates the environmental risks from the intended use of animal drugs and manages risks through labeling. FDA's authority applies to fish raised for human consumption, as well as to those fish used for stocking.

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[5] Because the authors experiment with inserting genes of one species into another species, these organisms can be considered transgenic.

The FDA approval process may involve granting investigative new animal drug exemptions (INADs) from approved use for the purpose of establishing data on which to base approval of a drug. Through the investigative approval process, the sponsor agrees to conduct laboratory and field tests with the drug under the conditions and on the animals proposed for approval. These data are collected in the INAD and eventually submitted to a new animal drug application (NADA) to form the basis for CVM's approval or disapproval of the drug. Data collection for the drug approval includes data on the observed or anticipated environmental effects associated with the drug's use. In the case of drugs used on aquatic animals the most significant environmental effect anticipated with the drug's usage is the effect on the aquatic environment.

Because granting an INAD and approving a NADA are federal actions, the FDA must comply with NEPA as it carries out these processes. INADs and NADAs require submission of either a claim of categorical exclusion or an environmental assessment (EA). 21 C.F.R. 25.15, 21 C.F.R. 511.1(b)(10), 21 C.F.R. 514.1(b)(10). Most INADs are categorically excluded but require that investigators contact appropriate NPDES offices before discharging drugs in aquaculture wastewater. Most NADAs for aquaculture drugs require EAs. The EA facilitates the environmental component of FDA's "safety" review by providing information relevant to determining whether environmental consequences resulting from use of the new animal drug could adversely affect the health of humans or animals and possibly render the drug unsafe. An EA includes detailed information on the use of the drug, its environmental fate (e.g., water solubility, octanol/water partition coefficient, sediment/particulate absorption, degradation), toxicity (e.g., acute and chronic effects on daphnia, vegetation, and fish), exposure calculations, and risk characterization (Eirkson et al., 2000). FDA attempts to post all environmental assessments and supporting materials for environmental assessments for all FDA approved aquaculture drugs on the FDA/CVM web site (http://www.fda.gov/cvm/default.html).

FDA has made several guideline documents available to sponsors that detail protocols and procedures for environmental studies. These documents aid sponsors in developing the data and information needed to ensure environmental safety. Guidelines currently available to drug sponsors include FDA Guideline documents #61 (addressing FDA approval of new animal drugs for minor uses and for minor species) and #89 (addressing environmental impact assessments (EIAs) for veterinary medicinal products (VMPs). These documents are available on the FDA/CVM web site. In addition, FDA has announced the availability for public comment of an additional guideline document produced by the Veterinary International Cooperation on Harmonization (VICH) (69 FR 21152, April 21, 2004). Presently, this draft guideline addresses issues such as cumulative impacts and is available at http://vich.eudra.org/pdr/10_2003/gl38_st4.pdf. FDA anticipates that following a public comment process, this guideline, like FDA guideline documents #61 and #89, would also become available to sponsors.

Despite the existence of these general protections, evaluation of site-specific conditions to determine potential for environmental impact may be appropriate for several reasons. Current FDA environmental assessment protocols, and presumably environmental assessments upon which they were based, do not contemplate all possible discharge scenarios (e.g., cumulative effects from multiple dischargers and/or repeated applications or cumulative exposure to chemical stressors that share the same mechanism of action). Furthermore, potential impacts of drug/pesticide discharges on specific sensitive, threatened, or endangered species that may be present in receiving waters of particular facilities may not have been evaluated. The potential for adverse impacts on non-target wild organisms due to incidental poisoning (e.g., adverse impacts to scavengers from consumption of medicated prey or carcasses) may also not be addressed by existing environmental review processes. In addition, advances in scientific understanding of environmental fate, transport, and effects of certain compounds may not be reflected in all environmental assessments and label requirements. Also, only limited information on environmental effects may be available for drugs used under INAD exemptions, or under extra-label use provisions, and the need for site-specific consideration of potential impacts may exist. One example of where this was true was in the use of cypermethrin at a net pen facility in Maine. Through FDA's INAD program, cypermethrin was tested as a treatment for sea lice on cultured salmon. In the facility's 2000 draft NPDES permit, EPA allowed the facility to discharge cypermethrin into the surrounding waters. Through the information collected by FDA for the INAD program, EPA determined that cypermethrin use could potentially lead to adverse impacts to non-target organisms passing through or beyond the net pens' mixing zone, even at dosages lower than what is required for sea lice treatment. As a consequence, EPA found the use of cypermethrin to be inconsistent with Maine's water quality standards and did not authorize its use in the facility's final permit. FDA has concluded that further research is needed before cypermethrin can be approved for use at aquaculture facilities (USEPA, 2002d).

Reviews of drugs and pesticides used in aquaculture have been published (e.g., GESAMP, 1997; Boxall et al., 2001). Although these reviews may have a broader focus than on practices in the United States, certain observations may have relevance to the United States. GESAMP (1997) reviewed chemicals used in coastal aquaculture, which include chemicals associated with structural materials, soil and water treatments, antibacterial agents and other therapeutic drugs, pesticides, feed additives, and anaesthetics. According to this review, most aquaculture chemicals, if properly used, can be viewed as wholly beneficial with no adverse environmental impacts or increased risks to aquaculture workers. However, the authors identified several factors that could make the use of otherwise acceptable chemicals unsafe: these include excessive dosage and failure to provide for adequate neutralization or dilution prior to discharge. Among potential environmental issues of concern relating to improper use are chemical residues in wild fauna, toxic effects in non-target species, and antibacterial resistance. The authors conclude with recommended measures to promote safe and effective use of chemicals in coastal aquaculture.

7.3.3.2 Environmental Effects Literature

Various sources of information are available for assessing potential effects of aquaculture drugs and pesticides. In addition to scientific literature that may be published for any drug or pesticide used by CAAP facilities, FDA's CVM posts environmental assessments and supporting materials for environmental assessments for all FDA approved aquaculture drugs on the CVM web site at *http://www.fda.gov/cvm/default.html*.

The USGS Midwest Environmental Sciences Center, Drug Research and Development Program conducts research to support the approvals (Food and Drug Administration) or registrations (U.S. Environmental Protection Agency) of drugs intended for use in public fish husbandry and management. More information about this program is available at *http://www.umesc.usgs.gov/aquatic/drug_research.html*.

In connection with the CAAP rulemaking, EPA has informally compiled environmental fate and effects literature for each of a group of drugs and pesticides used at CAAP facilities, drawing from a wide range of sources, including those identified above. These compilations include information on trade names, generally reported use and dosage, and tabulations of toxicity test data from a variety of sources.

The informal EPA compilations are in the electronic docket accompanying EPA's final CAAP rule (http://cascade.epa.gov/RightSite/dk_public_home.htm).

Below are brief discussions of some environmental effects information available for several drugs and a pesticide that were commonly reported as being used at CAAP facilities surveyed for EPA's final CAAP rule. These discussion were drawn from the sources described above as well as other sources. Interested readers are urged to consult the sources of information identified above, the primary literature cited in this section, as well as any other current scientific literature that may be relevant to a reader's application.

Hydrogen Peroxide

Hydrogen peroxide (H_2O_2) is used under an INAD exemption to control bacterial gill disease (FDA, 1998), and has also been used as a "low regulatory priority" drug to control fungi on all species and life stages of fish, including eggs (JSA, 2000). Recommended treatment concentrations for fungus control are up to 500 ppm for up to 60 minutes (Syndel, 2003); treatment methodologies are still being developed (JSA, 2000).

The USGS has assessed the potential environmental fate and effects of hydrogen peroxide use for treating external fungal, bacterial, and parasitic diseases (Howe et al., 2000). According to this report, hydrogen peroxide concentrations used in aquaculture facilities range from approximately 50 – 1,000 ppm. Hatcheries generally dilute the hydrogen peroxide concentrations by 2 to 100,000-fold before discharge into surface water. The decomposition rate of hydrogen peroxide in natural waters ranges from a few minutes to longer than a week, depending on the chemical, biological, and physical factors of the aquatic ecosystem. In most cases, according to the report, hydrogen peroxide concentrations in receiving waters should reach background levels within a few hours after discharge from a hatchery. The report noted that dilute concentrations of hydrogen peroxide could have short-term impacts on a variety of aquatic plants and animals but concluded that no long-term effects such as altered species composition or population densities would occur due to brief exposure times. The report also noted that no persistent contaminants would be discharged into the environment or would accumulate in aquatic organisms as a result of hydrogen peroxide release into aquatic environments. Other studies have shown hydrogen peroxide to be toxic to a variety of non-target organisms when exposed for 96 hours at relatively low concentrations (Tetra Tech, 2003). Ninety-six hour toxicity tests on *Ceriodaphnia dubia* performed by the California Department of Fish and Game yielded a maximum allowable toxicant concentration (MATC) of 1.77 mg/L (CDFG, 2002). The MATC is defined as the maximum concentration at which a chemical can be present and not be toxic to the test organism. It is the range of concentrations between the lowest observed effect concentration (LOEC) and the no observed effect concentration (NOEC)[6].

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[6] LOEC is the lowest treatment (i.e., test concentration) of a test substance that is statistically different in adverse effect on a specific population of test organisms from that observed in controls. NOEC is the highest treatment (i.e., test concentration) of a test substance that shows no statistical difference in adverse effect on a specific population of test organisms from that observed in controls. Note that the LOEC has to be less than the EC_{50}. If the LOEC is higher than the EC_{50}, then (1) the test has to be repeated to obtain a LOEC less than the EC_{50} or (2) the EC_{10} can be predicted from the dose-response curve (or the concentration-effect curve) (PBT Profiler, n.d.). EC_{50} (median effective concentration) is the statistically derived concentration of a substance in an environmental medium expected to produce a certain effect in 50 percent of test organisms in a given population under a defined set of conditions. The EC_{10} is the concentration where the effect is produced for 10 percent of the test organisms (McNaught and Wilkinson, 1997).

Formalin

Formalin is a solution of 37 percent formaldehyde gas by weight dissolved in water. The solution generally contains 10 to 15 percent methanol by weight to prevent polymerization (FDA, 1995). Formalin has been approved by FDA for use in several aquaculture applications under the trade names Formalin-F®, Paracide-F®, and Parasite-S®. Formalin is used to control fungi on finfish eggs and external parasites on finfish and shrimp. Treatment frequency, duration, and concentration varies with purpose of treatment, species, and culture conditions.

FDA has determined that no environmental impacts are expected, providing that treatment water is diluted adequately before being discharged to receiving waters (FDA, n.d.). FDA suggests that the concentrations of effluent from treatment tanks or raceways should be such that the concentration when diluted into the receiving waterbody is no greater than 1 ppm (FDA, 1995). In the finding of no significant impact for Parasite-S®, FDA requires a 10-fold dilution of finfish and penaeid shrimp treatment water and a 100-fold dilution of finfish egg treatment water, which should lead to a discharge concentration of no more than 25 ppm. FDA contended that additional in-stream dilution, infrequent use, and rapid degradation (formaldehyde, the active ingredient in formalin, is oxidized in the aquatic environment into formic acid and ultimately into carbon dioxide and water; the estimated half-life of formaldehyde in water is approximately 36 hours (FDA, 1995)) would render the discharged formalin below a level that causes significant environmental effects on aquatic animals (FDA, 1998). Directions for dilution of treatment water and additional environmental precautions are contained on the labeling of the product (FDA, n.d.).

In an environmental assessment performed in 1981 and submitted to FDA, U.S. Fish and Wildlife Service compiled results from several toxicity studies. USFWS noted that for most fish, formalin concentrations greater than 400-500 ppm cause mortality in 1 hour. No evidence of bioconcentration in fish tissue was found. Some fish prey organisms including daphnids (water fleas) and ostracods (seed shrimp) appear to be sensitive to formalin. In unusual circumstances, such as when effluent from fish treatment tanks or egg treatments are released into small, stagnant waterbodies, these releases would temporarily inhibit or damage phytoplankton and zooplankton populations, and contribute to hypoxic conditions. Any short-term inhibition or damage of these populations would be expected to recover rapidly (USFWS, 1981). Recent toxicity tests performed by the California Department of Fish and Game found the MATC is 2.7 ppm for the short term and 1.3 ppm for the long term (CDFG, 2002).

Oxytetracycline

Oxytetracycline has been approved by FDA to treat specific bacterial infections in catfish, salmonids, and lobster. It has also been approved to mark skeletal tissue in Pacific salmon so that resource management agencies can track salmon that are released to the wild. In the following listing of approved uses of oxytetracycline, minimum temperatures for treatment are specified (16.7˚C for catfish and 9˚C for salmonids) because temperatures below these minimums do not have approved withdrawal times. Clearance rates for oxytetracycline at lower temperatures and safe residual levels in tissues meant for human consumption are not known. Studies such as Meinertz et al. (2001) are being done to establish safe withdrawal times for treating aquatic animals which are meant for human consumption at lower temperatures. Other studies (e.g., Rigos et al., 2002) are being reported for determining the effectiveness and safety of treating other species with oxytetracycline.

Oxytetracycline is being used under an INAD for control of columnaris in walleye, vibriosis in summer flounder, and *Streptococcus* infection in tilapia (FDA, 1998). As stated earlier, the extralabel use of an FDA approved drug in or on feed is prohibited under AMDUCA. The Agency has granted regulatory discretion for the use of a medicated feed mixed according to the approval, for example oxytetracycline for salmon, to be used on or by the order of a veterinarian in an extra-label manner. The medicated feed cannot be modified in any way, for instance, it cannot be reformulated or repelleted. The medicated feed has to be labeled for the approved species and indication and only under a veterinarian's order can it be used extralabelly. For aquaculture this discretion applies only to those feeds approved for an aquaculture species.

In the *Finding of No Significant Impact for Terramycin (Oxytetracycline) Premix for Use in Lobster (NADA 38-439 C027)*, developed by Pfizer, Inc. (1987), it was determined that the potential for bioaccumulation or biomagnification of this compound in the environment was small (if it occurred at all). Pfizer (1987) also determined that there should be no development of resistance in environmental aquatic microorganisms resulting from the use of oxytetracycline at the levels prescribed under the NADA for use in lobster (Pfizer, Inc., 1987). This and other literature available from FDA and other sources suggest that environmental risk from therapeutic use of OTC for most applications is thought to be small and/or short term because OTC is likely to be well-chelated in the aquatic environment, among other reasons. It should be noted that a relatively small portion of oxytetracycline is actually retained by the target organisms. Instead, a large proportion of the drug administered in feed is thought to be lost to the environment (e.g., Smith et al.(1994); Smith (1996)). In addition, some researchers have further examined the possibility of the development of antimicrobial resistance in microorganisms (and other effects on microflora) in receiving water environments as a result of aquaculture medicated feed applications (see, e.g., Austin, 1985; Bebak-Williams et al., 2002). Please see these sources for further discussion of this issue.

Kerry et al. (1996) found detectable quantities of oxytetracycline beneath and near Atlantic salmon net pens and elevated levels of oxytetracycline-resistant bacteria. Capone et al. (1996) found oxytetracycline levels in sediments were correlated to facility usage. Capone observed oxytetracycline residues in edible wild crab meat collected under net cages that had undergone high levels of oxytetracycline treatment and noted that farm employees occasionally collected crabs for consumption. The levels observed in Capone's study exceeded FDA allowable tissue residue levels. Capone noted that health risks associated with ingesting food containing antibacterial residues are unclear and highly controversial but levels in excess of FDA levels suggest that the issue merits further attention. Although these and other studies show the presence of oxytetracycline in sediments or aquatic species below net pens, it is important to note that practices used at the time of the studies and the studies themselves are relatively old, that oxytetracycline use has declined since the studies were conducted, and that some of the high readings were from a facility that may have had anomalous application rates.

In sampling done at 13 hatcheries, antibiotics were only detected in effluent waters from five of the facilities (Thurman, et al., 2002). However, sampling was not timed to coincide with antibiotic treatments; antibiotic concentrations could be higher during periods of treatment. Oxytetracycline and sulfadimethoxine, the most frequently detected antibiotics, were found at concentrations in the range of 0.10- to 2.0 μg/L, with only two samples exceeding this range (10 μg/L oxytetracycline in one sample; >15 μg/L sulfadimethoxine in one sample). No antibiotics were found in samples taken from source water at the hatcheries. (Thurman, et al., 2002).

According to MacMillan (2003), no data currently exists to demonstrate a direct link between the use of antibiotics in aquaculture and the occurrence of human pathogens that are resistant to antibiotics. According to the author, only very limited data exists that documents the concentration of antibiotics in water as a consequence of the use of antibiotic medicated feed, and studies continue to be conducted to determine the potential impact of specific aquaculture drugs in the environment.

Copper

Copper, primarily in the form of copper sulfate ($CuSO_4$) and chelated copper (organically complexed copper) compounds, have been used for many years as a pesticide to control unwanted algae in ponds, tanks, and raceways. Copper compounds are also used as an antifoulant treatment for the nets used in net pen operations (Nash, 2001). Flexabar Aquatech's Flexgard is a latex algaecide dip designed for treating nets. The active ingredient in the dip is cuprous oxide (26%), which is highly toxic to fish and crustaceans (Flexabar Aquatech, n.d.; EAO, n.d.; PAN, n.d.).

Copper sulfate is also being tested (as an INAD) for use in the treatment of external parasites. More specifically, it is used to control bacterial diseases, fungal diseases, and external protozoan and metazoan parasites in finfish (Plumb, 1997). Copper sulfate has been used experimentally to treat fish parasites such as *Ichthyophthirius* (Ich), *Trichodina*, *Icthyobodo* (Costia), *Trichophyra*, *Chilodonella*, *Ambiphrya* (Scyphidia), *Apisoma* (Glossatella) and fungus (Masser and Jensen, 1991).

Copper is extremely toxic to aquatic organisms. It may be poisonous to trout and other fish, especially in soft or acidic waters, even when it is applied at recommended rates. Copper's toxicity to fish tends to decrease as water alkalinity increases. Fish eggs are more resistant to the toxic effects of copper than young fish fry. Copper is also toxic to aquatic invertebrate such as crabs, shrimp, and oysters (Extoxnet, 1996). For more information, refer to EPA's *Ambient Water Quality Criteria for Copper - 1984* (USEPA, 1985).

Copper is adsorbed to organic materials and to clay and mineral surfaces. The degree to which it is adsorbed depends on the acidity or alkalinity of the soil (Extoxnet, 1996). USDA cites Baudo et al. (1990) as saying: "The bioavailability of copper is regulated by water pH, sediment pH, sediment redox potential, acid volatile sulfides, sediment and waterborne organic carbon, particle size distribution, clay type and content, and cation exchange capacity of the sediment" (USDA, 1997).

Levels of copper around some net pen facilities may be elevated when it is used as an antifouling agent for the nets. According to Nash (2001), there is no evidence of long-term buildup of copper under salmon farms. As stated by Nash (2001), Lewis and Metaxas (1991) examined copper concentrations inside and immediately next to newly installed copper-treated nets at a net pen salmon farm in British Columbia. According to the authors, tidal exchange in and near net pens is important in maintaining low dissolved copper concentrations by preventing the accumulation of copper leached from nets. As reported in Nash (2001), Brooks (2000) stated that sediment copper concentrations at farms using copper treated nets were not always associated with the copper treatment itself but with other activities such as net washing, which can abrade copper-latex paint off the nets. Because of this, Brooks (2000) advised that any copper-treated nets should be washed and retreated at upland stations with any residual debris being buried at approved landfill sites.

Han et al. (2001) investigated the accumulation, distribution, and potential bioavailability of copper in sediments in catfish ponds that received weekly copper sulfate applications during summer growing seasons over 3 years. There was significant accumulation of copper (45.5 mg/kg/yr) in pond sediments at the end of the study, and the copper was not evenly distributed in pond sediments. Copper also accumulated with possible greater bioavailability in the copper sulfate treated ponds than non-treated ponds. Han et al. found that over time copper will redistribute through the soil as more and more stable fractions, thus reducing bioavailability.

Huggett et al. (2001) investigated the fate and effects of copper sulfate on non-target biota in streams that receive catfish pond effluent containing copper. Upstream and outfall samples did not adversely affect the test organisms used (*Hyalela azteca* and *Typha latifolia*), but the downstream samples did adversely affect *Hyalela azteca* survival. *Typha latifolia* germination and growth was not affected by the downstream sediment; however, shoot growth did decrease with increasing concentrations of copper. Effects of different sediment concentrations in this study may differ from other studies due to differences in sediment characteristics. Organic carbon and particle size, for example, greatly influence the bioavailability of copper in stream sediment.

7.3.4 Impacts from Pathogens

Although aquaculture facilities are not considered a source of human pathogens (see Section 7.2.6), it is possible that pathogens from other sources (e.g., mammals or birds) may be present in waste storage areas. MacMillan (2002) indicates that this is a unlikely source of risk. Nash (2003) also notes that there is little evidence to suggest that the accumulation of wastes from net-pen facilities is a source of human or environmental pathogens. Although some monitoring has showed a slight increase of fecal coliform near salmon farms, it is likely that these bacteria are from mammals or birds in the area.

It has also been suggested that aquaculture operations may be a source of disease to wild populations. Nash (2003) discusses the low risk that escaped Atlantic salmon would be vectors for the introduction of new, exotic pathogens into the Puget Sound area of Washington State. No new stocks of Atlantic salmon have been transferred into Washington since 1991, and any stocks transferred within the State must have a certification that they are disease-free, so it is not possible that Atlantic salmon already in the state would be vectors for exotic disease (Nash, 2003). Because all farmed salmon in Washington State are inspected annually for disease, they do not present a high risk for infection of wild stocks (Nash, 2003). While fish hatcheries may potentially be reservoirs of infectious agents (due to higher rearing densities and stress), little evidence suggests that disease transmission to wild stocks from hatcheries occurs routinely (Strom et al., n.d.).

In British Columbia, the Environmental Assessment Office (EAO) of British Columbia reported that between 1991 and 1995, 90 adult Atlantic salmon recovered in British Columbia and Alaska were examined to determine if they were infected with any diseases. Two fish were infected with *Aeromonas salmonicida*, the causative agent of furunculosis, and none of the fish contained unusual parasite infestations. Additionally, none of the tested fish were infected with common viral infections (Alverson and Ruggerone, 1998). In contrast, a recent study in British Columbia by Morton et al. (2004) showed an increased incidence of sea lice (*Lepeophtheirus salmonis*) in wild juvenile pink (*Oncorhynchus gorbuscha*) and chum (*O. keta*) salmon near net pen farms in the Broughton Archipelago of British Columbia. Morton et al. found that 90% of the pink and chum salmon sampled near net-pen farms were infected above the lethal limit for lice in the mobile stage. They also showed that the abundance of sea lice infestations were 8-times greater near net pens than in control sites, and that in areas with no farms the sea lice numbers were close to zero. According to the author, although the study does not provide a causal relationship between salmon farms, sea lice, and wild salmon infection rates, the findings do suggest the salmon farms are a source of sea lice in this region (Morton et al., 2004). It is important to remember that the density of net-pen aquaculture operations in the British Columbia area is much greater than that in the U.S. coastal waters of the Pacific Northwest.

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